HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District 5183d

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
CERTIFIED RETURN RECEIPT

February, 3, 2005 W/L: 10-05

Kelly A. Donavan, Owner
The Byran Company, Inc.
18092 Redondo Circle
Huntington Beach, CA 92647

Dear Mr. Donavan:

An inspection of your firm conducted on September 16, 22, 28, and 30, 2004 revealed that your firm is a manufacturer of Class I and Class II implantable surgical spine screws, rods and other orthopedic devices used during surgery. These products are finished devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)] because they are suitable for use or are capable of functioning whether or not they are packaged, labeled or sterilized. 21 Code of Federal Regulations (CFR) 820.3(l). Thus, the Quality System regulation, 21 CFR Part 820, applies to their manufacture.

The above-stated inspection revealed that your devices are adulterated within the meaning of Section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System regulation.

Significant violations include, but are not limited to, the following:

1. Failure to establish and maintain a quality system that is appropriate for the specific medical devices being manufactured by your firm, as required by 21 CFR 820.5.

For example, during our inspection, your firm stated that it does not have a quality system.

2. Failure to establish a management representative, as required by 21 CFR 820.20(b)(3).

   For example, during our inspection, your firm stated that it has not designated a management representative.

3. Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a).

   For example, during our inspection, your firm stated that it does not have a corrective and preventive action procedure.

4. Software validation activities for your automated computer system used as part of production have not been performed or documented for its intended use according to an established protocol, as required by 21 CFR 820.70(i). Specifically, the software used for setting the specifications for screws and other medical devices has not been validated.

   For example, during our inspection, your firm stated that a written protocol for software validation does not exist and records of such validation activities do not exist.

5. Failure to establish and maintain procedures for receiving, reviewing and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198.

   For example, during our inspection, your firm stated that it does not have a procedure to review or evaluate complaints involving the possible failure of a device.

6. Failure to define complaint handling procedures to ensure that all complaints are evaluated to determine whether the complaint should be filed as a Medical Device Report, as required by 21 CFR 820.198(a)(3).

   For example, during our inspection, your firm stated that it does not have a Medical Device Reporting (MDR) procedure.

7. Failure to establish and maintain procedures to control documents, as required by 21 CFR 820.40.

   For example, during our inspection, your firm stated that it does not have a procedure for document control.

8. Failure to establish and maintain procedures for quality audits and conduct such audits, as required by 21 CFR 820.22.

   For example, during our inspection, your firm stated that it does not have a quality audit procedure, does not conduct such audits, and did not maintain records of such audits.

9. Failure to establish a quality plan which defines how the requirements for quality will be met, as required by 21 CFR 820.20(d).

   For example, during our inspection, your firm stated that it does not have a quality plan.

The above stated inspection also revealed that your devices are misbranded under section 502(t)(2) of the Act (21 U.S.C. 352(t)(2)), in that your firm failed to furnish material or information as required under section 519 of the Act (21 U.S.C. 360i) and regulations implementing that section at 21 CFR Part 803 – Medical Device Reporting. Significant violations include, but are not limited to, the following:

1. Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17.

   For example, your firm stated during the inspection that it does not have an MDR procedure for evaluating adverse events and submitting the required reports to FDA.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. For instance, adverse events involving devices manufactured by your firm were reported by user facilities and/or voluntary reporters. The MDR events include but are not limited to screws breaking in patients causing pain and additional surgery. The investigator discussed these events with you during the inspection to ensure conformance with the Quality System regulation.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter please contact Compliance Officer, Deborah Greco at 949-608-2959. You may obtain general information about all of FDA's requirements for manufacturers of medical devices through the Internet at http://www.fda.gov.

Sincerely,

Alonza E. Cruse
District Director